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09/029,872 06/29/98 PUGH

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EXAMINER

PAPER NUMBER
ART UNIT

3738
 DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/029,872	Applicant(s) Pugh et al
	Examiner Paul Prebilic	Group Art Unit 3738

Responsive to communication(s) filed on Jan 19, 2001.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-3, 5, 6, 10-15, 19-35, and 37 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) 10, 20, and 37 is/are allowed.

Claim(s) 1-3, 5, 6, 11-15, 19, and 21-35 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, 11-15, 21-23, 31, and 33-35 are rejected under 35 U.S.C. 102(a) or 102(b)* as being anticipated by Davies (WO 94/26872). Davies discloses a sintered hydroxyapatite and tricalcium phosphate film on quartz (see pages 26-28). This procedure is identical to the present specification's manner of stabilizing hydroxyapatite due to the silica of quartz permeating into the sol during sintering; see Procedure 3 on page 30 of the present specification and note that only the bulk ceramic pieces need to be doped with a stabilizer because the quartz substrate inherently dopes the sol-gel. The Examiner posits that the stabilization of hydroxyapatite is not mentioned by Davies, nonetheless, this property is inherently present because it is made the same way as in the present specification; see also pages 6, 7, and 15 of Davies.

*The Examiner posits that the effective filing date of the present claims is August 30, 1996 because the provisional application 60/003,157 and the earlier parent application 08/576,238 only disclosed silicon entities and not other types of entities as the present claims do. Therefore, the present claims have a later filing date because the term stabilization or the meaning of stabilization entities was broadened from the meaning it had in the parent application filed before August

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30, 1996. Alternatively, if the earlier date for the claims has support, the Davies constitutes a 35 USC 102(a) reference.

Claims 1-3, 12-14, 19, 22, 23, 31, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasuga et al (US 5,232,878) wherein the stabilizing entities are the alkaline earth metal silicates of the second step where hydroxyapatite is used. Also, zirconia and alumina may serve as stabilization entities in the fourth step; see the whole document, especially the abstract, Col. 1, lines 5-10; Col. 3, lines 3-37; Col. 5, line 9 to Col. 6, line 24; Col. 6, lines 64-67 and Col. 8, lines 56-61.

Claims 1-3, 5, 6, 11-14, 21, 23, 24, and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Kijima et al (US 4,983,182) wherein zirconia is used to stabilize hydroxyapatite to the extent required by the present claims; see the whole document.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-30 and 32 are rejected under 35 U.S.C. 102(a) or 102(b)* as anticipated by Davies (WO 94/26872) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Davies (WO 94/26872) alone.

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With regard to claims 24-26 and 32, Davies anticipated the claim language wherein the Examiner posits that the same structure must exist therein due to the fact that it is made in the same manner as the disclosed and claimed invention of the present claims. Davies even discloses that the material can be porous; see page 21. Alternatively, the Examiner posits that the claimed product is at least substantially identical to that disclosed by Davies such that the claimed invention is clearly obvious; see MPEP 2113 which is incorporated into this Office action by reference.

With regard to claims 27-29, the Examiner posits that the claimed matrix would inherently be present in the Davies device due to the same device being exposed to the same cells for a sufficient time for such matrix to form. Alternatively, the Examiner posit that the claimed matrix is at least obvious in view of Davies alone due to its clearly similar method of making.

Allowable Subject Matter

Claim ¹⁰ 1, 20, and 37 are allowed over the prior art of record.

Response to Arguments

Applicant's arguments filed January 19, 2001 have been fully considered but they are not persuasive. Specifically, the arguments the prior art did not contemplate the use of the quartz substrate as a stabilizer are unpersuasive because something that is old cannot become patentable upon the discovery of a new property; see MPEP 2112 and *In re Best*, 195 USPQ 430, 433 (CCPA 1977). The same sort of arguments are used in the traversal of the Kasuga et al rejection; however, the Examiner posits that such arguments are equally not persuasive for the same reasons

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as cited in support of the Davies rejection. As pointed out in the rejection, Applicants disclose the same method of using a quartz substrate with a sol on page 30 of the specification (see Procedure 3) as that disclosed by Davies. Since the claims encompass this embodiment, it is reasoned that the claims are anticipated by Davies since Davies also falls within the claim scope also.

In the traversal of the Kasuga, Applicants argue that the term "bioactive" refers to the ability to support osteoblastic bone growth over and throughout structures made of the composition. However, the specification does not place a restriction on the definition of the term, rather, it only sets forth certain elements which can fall within the scope of the term. For this reason, the Examiner has given "bioactive" its ordinary meaning because the specification clearly does not change it to anything else. As a result, the arguments in this regard are considered to be unpersuasive.

Applicants argue that the Kasuga implant does not support bone cell activity, but since no evidence of this is provided, it is considered to be a mere allegation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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